WEB Table 1: Summary of BBP General Toxicity, Male Rats

Strain	Experimental Regimen	Number	Dose (mg/kg/day)	Body Weight	Organ Weight	Histopathology	Hematopoietic System	Chemistry	Other
Fischer 344 [Agarwal, 1985 #10]	Adult male rats were fed diets with BBP for 14 days and sacrificed and necropsied.	10	0						
		10	447[a]	NE	↑Li and Ki	NE	NE	↑LH	NE
		10	890[a]	NE	↑Li and Ki	NE	NE	NE	NE
		10	1338[a]	↓	↓Te and SV ↑Li and Ki ↓Th	Dose-related increase in severity of morphological changes in seminal vesicles, testes and prostate	↓ bone marrow cellularity	↑FSH ↑LH	↓ food consumption
		10	1542[b]	↓	↓Te, SV, Ep ↑Li, Ki ↓Th	Mild multifocal chronic hepatitis in liver. Cortical lymphocytolysis in thymus (atrophy)	↓ bone marrow cellularity	↓Test ↑FSH ↑LH	↓ food consumption

[a] Doses calculated using pre-treatment body weights (200 g) and average food consumed per group during 14 day study.
[b] Dose calculated from average body weight during study (since there was a weight loss) and food consumed during the 14 day study.

NE = No effects
↑= Statistically significant increase
↓=Statistically significant decrease
Li = Liver
Ki = Kidney
Th = Thymus
Te = Testes
Ep = Epididymis
SV = Seminal Vesicle

WEB Table 2: BBP General Toxicity, Rats

Strain	Experimental Regimen	Number/ sex	Dose (mg/kg/day)	Body Weight	Organ Weight[a]	Histopathology	Hematology	Chemistry	Other
Sprague-Dawley Rat	Four to six-week-old rats were fed diets with BBP for 3 months and sacrificed and necropsied.	10	0						
		10	188	NE	NE	NE	NE	NA	
		10	375	NE	NE	NE	NE	NA	
		10	750	NE	↑Ki(M),Li(F)	NE	NE	NA	
		10	1125	↓ (M)*	↑Ki(M),Li	NE	NE	NA	
		10	1500	↓*	↑ Ki(M),Li	NE in liver, testes, or pancreas	NE	NA	
Wistar Rat	Four to six-week-old rats were fed diets with BBP for 3 months and sacrificed and necropsied.	27-45	0						
		27-45	151(M)-171(F)	↓(M)*	↑Li and Ce(F)	NE	NE	NE	
		27-45	381(M)-422(F)	↓*	↑Li and Ce(F), Ki	Pancreatic lesions	NE	NE	↓Urinary pH (M)
		27-45	960(M)-1069(F)	↓*	↑Ce (F), Li, Ki	Hepatic necrosis and pancreatic lesions	Anemia (M)	NE	↓Urinary pH (M)
Sprague-Dawley Rat	Six to eight-week-old rats inhaled BBP mists for 6 hours/day, 5 days/week for 13 weeks, then sacrificed and necropsied.	25	0						
		25	9.2(M)/9.8(F)	NE	NE	NE	NE	NE	
		25	39.4(M)/42(F)	NE	NE	NE	NE	NE	
[Hammond, 1987 #229]		25	143(M)/152(F)	NE	↑Li, Ki	NE	NE	↓ Serum glucose (M, 13 wk)	

*Statistical significance is unknown

[a] Organ to body weight ratio

NA=Not analyzed
NE=No effect
↑= Statistically significant increase
↓=Statistically significant decrease

M=Male
F=Female
Li=Liver
Ki=Kidney
Ce=Cecum
wk=Week

Last updated on 6/9/00

WEB Table 3: BBP General Toxicity, Male Rats

Strain	Experimental Regimen	Number	Dose (mg/kg/day)	Body Weight	Organ Weight	Histopathology	Epididymal Sperm Count	Hematology	Other
Fischer 344/N [NTP, 1997 #543]	Sub-chronic study (26 wk) Six-week-old male rats fed diets with BBP, hematological measurements taken every 30 days. Rats were killed and necropsied at the end of the study, epididymal sperm counts.	13	0						
		14	30	NE	NE	NA*	NA	NE	
		14	60	NE	NE	NA	NE	NE	
		14	180	NE	NE	NA	NE	NE	NOAEL
		15	550	NE	↑Li[b]	NE*	NE	↑Hg day 60-180	LOAEL
		11	1650[a]	↓	↑Li, Ki[b] ↓Te[b] ↓SV, Ep[c]	Testicular and epididymal degeneration and seminiferous tubule atrophy	↓ Sperm counts	↑Macrocytic anemia days 30-180.	

[a] The dose for the highest exposure level could not be calculated but was estimated from lower doses, assuming equal body weight and food intake.
[b] Organ to body weight ratio
[c] Absolute organ weight

* Per CMA: There was an error in the original NTP report regarding the dose levels that histopathology was examined at.

NA=Not analyzed
NE=No effects
↑= Statistically significant increase
↓=Statistically significant decrease
M=Male
F=Female
Li=Liver
Ki=Kidney
Te=Testes
Ep=Epididymis
SV=Seminal Vesicle
Hg=Hemoglobin

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WEB Table 4: BBP General Toxicity, Rats

Strain	Experimental Regimen	Number	Dose (mg/kg/day)	Body Weight	Organ Weight[a]	Histopathology	Hematology	Chemistry	Other
Fischer 344/N [NTP, 1997 #543]	Six-week-old rats were fed diets with BBP for 2 years. Hematological analysis was conducted at 6, 8, and 15 months and hormone levels were measured at 6, 15, and 24 months. Organ weights were measured at 15 months and histopathology was evaluated at 15 and 24 months.		0 **Male:**						
		60	120	NE	↑Ki	NE	NE	NE	
		60	240	↓	↑Ki ↑Ep	NE	NE	NE	
		60	500	↓	↑Ki, Li ↑Ep	Renal tubule pigmentation (15-24 mo) Hepatic granuloma (24 mo) No testicular effects Focal pancreatic hyperplasia and *some evidence* of pancreatic carcinogenicity	↓RBC (6 mo) ↑Hg (6 mo)	NE	↑Skin lesions
			Female:						
		60	300	NE	NE	Nephropathy (24 mo)	NE	NE	
		60	600	NE	NE	Nephropathy (24 mo)	NE	NE	
		60	1200	↓	↑Ki, Li	Renal tubule pigmentation (15- 24 mo) Nephropathy (24 mo) *Equivocal evidence* of pancreatic and urinary bladder carcinogenicity	↑Microcytic anemia (15 mo)	↓Triiodothyronine (6-15 mo)	

[a] Organ to body weight ratio

NA=Not analyzed ↑= Statistically significant increase M=Male Ep=Epididymis Ki=Kidney mo=Month
NE=No effects ↓=Statistically significant decrease F=Female Li=Liver RBC=Red Blood Cell Hg=Hemoglobin

Last updated on 6/9/00

WEB Table 5: BBP Developmental Toxicity, Rats

				Effects	
Strain	**Experimental Regimen**	**Number**	**Dose (mg BBP/kg bw/day)**	**Maternal**	**Fetal**
CD Rat	Prenatal developmental toxicity study.	28	0		
[Field, 1989 #157]	BBP administered in feed on gd 6-15.	27	420	Maternal NOAEL	Developmental NOAEL
	Sacrificed on gd 20. Dams weighed on gd 0, 3, 6, 9, 12, 15, 18, and 20.	30	1100	↓ Weight gain (37%) ↑ Liver to body weight ratio ↑ Food and water intake	↑ Fetuses with variations/litter (41 vs 19%)
	Maternal liver, kidney, and intact uterus were weighed, corpora lutea were counted and implantation sites examined. All fetuses were weighed and examined for gross external, visceral, and skeletal malformations.	29	1640	↓ Weight gain (93%) ↓ Corrected weight gain (17%) ↑ Liver to body weight ratio with no pathological effects ↑Kidney to body weight ratio ↑ Food and water intake Clinical signs of toxicity	↓ Fetal Weight (20%) ↓ Live fetuses/litter (n=10 vs 15) ↑ Resorptions/litter (40 vs 4%) and litters with resorptions (86 vs 32%) ↑ Fetuses with variations/litter (71 vs 19%) ↑ Fetuses with malformations (53 vs 2%); Litters with malformations (96 vs 25%) (visceral, external, and skeletal, especially of the urinary tract, eyes, and spine.

WEB Table 6: BBP Developmental Toxicity, Rats

				Effects	
Strain	**Experimental Regimen**	**Number[a]**	**Dose (mg BBP/kg bw/day)**	**Maternal**	**Fetal**
Wistar Rats	Prenatal developmental toxicity study. Rats were fed diets with DBP from gd 0-20. Body weights and food intake were measured daily. Dams were sacrificed on gd 20. Implantation sites were examined. Pups were sexed, weighed, and evaluated for external malformations. Two-thirds of fetuses were examined for skeletal malformations and 1/3 for visceral malformations.	15 (15)	0		
[Ema, 1990 #145]		17 (17)	185	No effects	No effects
		15 (15)	375	NOAEL ↓Weight gain (15%)	NOAEL ↑Fetal weight (2.5-5%) ↓Live fetuses/litter (n=11.3 vs 13.9)
		13 (13)	654	↓Weight gain (35%) ↓ Adjusted weight gain (96%) ↓Food Intake	↓Fetal weight (7%)
		13 (0)	974	Weight loss (15 g) Adjusted weight loss (21 g).[b] ↓Food Intake	Complete postimplantation loss in all litters Treatment-related increase in malformations, variations, or retardations were not seen at any dose.

[a] Number of pregnant rats (Number of litters evaluated). [b] Body weight not including gravid uterus weight.

WEB Table 7: BBP Developmental Toxicity, Rats

				Effects	
Strain	**Experimental Regimen**	**Number[a]**	**Dose (mg BBP/kg bw/day)**	**Maternal**	**Fetal**
Wistar Rats [Ema, 1992 #137]	Prenatal developmental toxicity study. Rats were gavaged with BBP from gd 7-15. Body weights and food intake were measured daily. Dams were sacrificed on gd 20. Implantation sites were examined. Pups were sexed, weighed, and evaluated for external malformations. Two-thirds of fetuses were examined for skeletal malformations and 1/3 for visceral malformations.	10 (10)	0		
		10 (10)	500	NOAEL ↓ Food intake.	NOAEL
		10 (7)	750	↓ Body weight gain. ↓ Food intake.	Complete resorption loss in 3/10 litters. ↑ Fetal death/litter (n=11 vs 1) ↑ Postimplantation loss/litter (82 vs 8%). ↓ Fetal weight (18%). ↑ External (12 fetuses/7 litters vs. 0), skeletal (5 fetuses/4 litters vs. 1), and internal (3 fetuses/3 litters vs. 0) malformations.
		10 (0)	1000	↑ Death (4 dams). ↓ Corrected body weight gain.[b] ↓ Food intake.	Complete resorption in 6/6 litters.

[a] Number of pregnant rats (Number of litters evaluated). [b] Body weight not including gravid uterus weight.

WEB Table 8: BBP Developmental Toxicity, Mice

				Effects	
Strain	**Experimental Regimen**	**Number**	**Dose (mg BBP/kg bw/day)**	**Maternal**	**Fetal**
CD-1 Mice	Prenatal developmental toxicity study.	29	0		
[Price, 1990 #524]	BBP administered in feed on gd 6-15.	28	182	Maternal NOAEL	Developmental NOAEL
	Sacrificed on gd 17. Dams weighed on gd 0, 3, 6, 9, 12, 15, 17. Maternal liver, kidney, and intact uterus were weighed, corpora lutea were counted and implantation sites examined. All fetuses were weighed and examined for gross external, visceral, and skeletal malformations.	30	910	↓ Weight gain (15%)	↑ Late fetal deaths/litter (2.9 vs 0.7%) ↑ Non-live implants/litter (15 vs 8%)[a] ↓ Live fetuses/litter (n=12 vs 13) ↑ Fetuses/litter with malformations (14 vs 4%); Litters with malformations (60 vs 31%)
		27	2330	↓ Weight gain (71%) ↓ Corrected weight gain (25%) ↑ Water and food intake ↑ Liver and kidney to body weight ratio with no pathological effects	↑ Resorptions/litter (91 vs 7%); Litters with resorptions (100 vs 55%) ↑ % Non-live implants/litter (93 vs 8%); Litters with non-live implants (100 vs 59%)[a] ↓ Live fetuses/litter (n=3 vs 13) ↓ Fetal weight (17%) ↑ Fetuses/litter with malformations (89 vs 4%) ↑ Litters with malformations (100 vs 31%), especially external and skeletal defects of the tail, ribs, sternebrae and vertebrae ↑ Fetuses with variations/litter (98 vs 29%)

[a] Non-live implants include resorptions and late fetal deaths

WEB Table 9: BBP Developmental Toxicity, Rats

				Effects	
Strain	**Experimental Regimen**	**Number**[a]	**Dose (μg/L)**	**Maternal**	**Fetal**
Wistar Rat	Pre and postnatal developmental toxicity study.	5	0		
[Sharpe, 1995 #696]	Female rats were exposed to BBP through drinking water for 2 weeks prior to mating, and during mating, gestation and lactation. Rats were mated to untreated males. Dams were allowed to litter. Litter sizes were evaluated at birth. At 90-95 days of age, male offspring were sacrificed and organ weights were determined.	5	1000	No assessment of maternal toxicity	↑ Body weight on pd 22 (11%) ↓ Absolute testes weight (10%) and testes to body weight ratio (8%)
		6	100[b] *DES*		¯*Body weight on pd 22* ¯*Absolute testes weight and testes to body weight ratio*
	After the first litters were weaned, the experiment was repeated in the same dams. Additional parameters monitored included testicular morhphology in 2 pups/group and sperm counts in 7-12 pups/group.	6	*0*		
		5	1000	No assessment of maternal toxicity	↑ Body weight on pd 22 (14%) ↓ Absolute testes weight (7%) and testes to body weight ratio (7%) ↓ Daily sperm production (~10-21%)
		5	100[b] DES		- *Body weight on pd 22* ¯*Absolute testes weight and testes to body weight ratio* ¯*Daily sperm production*

[a] Total litters evaluated. The number of treated dams was not stated.

[b]Positve DES control

WEB Table 11: BBP Developmental Toxicity, Rats

Strain	Experimental Regimen	Number	Dose (μg/L)	Effects	
				Maternal	**Fetal**
Wistar Rat	Pre and postnatal developmental toxicity study.	25	0		
[TNO, 1998 #611]	Female rats were exposed to BBP through drinking water for 2 weeks prior to mating, and during mating, gestation and lactation. Rats were mated for 1 week to untreated males, that were only exposed to BBP while breeding. Body weights and food intake were measured weekly and water intake was measured daily. Dams were allowed to litter and following weaning of pups, were killed, necropsied, and implantation sites were examined. Pups were weighed, examined for abnormalities, evaluated for sexual maturation and function, and necropsied at 89-101 days of age.	23	100	No effects	No effects
		22	1000	NOAEL	↑Pup death on pd 1-4 (n=29 vs 2) (Pup death/litter not significant) ↑Large pups (pd 4)
		24	3000	↑Hair loss at necropsy ↑Pre-mating weight gain ↓Water intake (gd 1; pd 7 and 9) No effects on postimplantation loss, mating, fecundity, fertility, or gestation index.	↑Pup death on pd 1-4 (n=39 vs 2) (Pup death/litter not significant) ↑Cold pups (pd 1) ↑Large pups (pd 4) ↑Hair loss No effects on sperm morphology, number, or motility; estrous cycles; or sexual maturation at any dose level.
		21	10-50 DES[a]	↓Gestational weight gain ↑Duration of pregnancy	↑Pup death (pd 1-4) ↓Live pups/litter ↓Decreased weight gain ↑Age of preputial separation ↓ Normal sperm ↓Sperm count (significance not known) ↓Testes weight
	The study was repeated with BBP to verify postnatal pup deaths	26	0		
		22	1000	Not Reported	↓Pup death on pd 1-4 (n=11 vs 29)
		24	3000		↑ Pup death on pd 1-4 (n=42 vs 29) ↑Stillborn pups (n=28 vs 13) (Both effects/litter were insignificant)

[a]Positive DES control.

WEB Table 10: BBP Developmental Toxicity, Rats

				Effects	
Strain	**Experimental Regimen**	**Number**	**Dose** (μg/L)	**Maternal**	**Fetal**
Wistar AP Rat [Ashby, 1997 #37]	Pre and postnatal developmental toxicity study. Rats were exposed to BBP through drinking water during gestation and lactation (gd 1-pd 20). Body weights were measured on gd 1, 4, and 22 and pd 3, 7, 14, and 20. Water intake was measured daily. Dams were allowed to litter and following weaning of pups, were killed and necropsied. Liver enzyme activity, hematology, and micronucleated erythrocytes were assessed. Pups were sexed, weighed, and evaluated for sexual maturation. Uterotrophic effects were examined in groups of 10 female rats on pd 21 and 24. The majority of pups were sacrificed and necropsied on pd 90 and 10 males/group were sacrificed on pd 137. Sperm analysis was conducted at necropsy. FSH-positive pituitary cells were counted in 9 rats/sex	19 18 *5*	0 1000 *50 DES*[a]	 No effects *¯Body weight*	 ↑ Male pup weight on pd 2 (13%) ↑ Anogentital distance in males on pd 2 (4%)[b] ↓ Age of vaginal opening (34 vs 35.1 days)[b] ↑ Liver to body weight ratios in males (4%) No effects on sperm counts, testes weight, or premature uterine development. *¯Body weight* *-Uterine weight and uterotrophic response* *-Absolute ovarian weight* *¯Anogenital distance in males and females* *¯Age of vaginal opening* *-Age of preputial separation* *¯Decrease testis, epididymis, seminal vesicle, and prostate weight* *¯Decreased sperm count*

[a] Positive DES control [b]Authors considered effects to be related to increased pup weight

WEB Table 12: BBP Developmental Toxicity, Rats

				Effects	
Strain	**Experimental Regimen**	**Number***	**Dose (µg/L water or Kg food)**	**Maternal**	**Fetal**
Wistar Rat	Pre and postnatal developmental toxicity study.	21-22	0		
[Bayer, 1998 #955]	Female rats were exposed to BBP through drinking water or diet for 2 weeks prior to mating, and during mating, gestation and lactation. Rats were mated for up to 3 weeks to untreated males, that were only exposed to BBP while breeding. Body weights and food and water intake were measured every 3-7 days. Dams were allowed to litter and following weaning of pups, were killed, necropsied, and examined for implantation sites. At birth, pups were counted, weighed, and examined for abnormalities. Pups were evaluated for survival and weight gain until postnatal day 21, when they were sacrificed and necropsied.	22-25 24	1000 3000	No significant effects on fertility, body weight gain or food and water intake.	Non-significant increase in resorptions in both dose groups. No significant effects on litter size, pup viability from birth to postnatal day 4, and pup weight.

*Number of females that gave birth to a live litter/exposure media

WEB Table 13: BBP Reproductive Toxicity, Rats

Strain	Experimental Regimen	Dose (mg BBP/kg bw/day)	Effects		
			Paternal	Maternal	Litter
WU Rat [Piersma, 1995 #514]	Toxicity and Reproduction screening study. BBP administered by gavage to male and females rats for two weeks prior to mating. Males were dosed for a total of 29 days and females were dosed until pd 6. Rats were housed together 1:1 for a maximum of 2 weeks. Body weight and food intake were measured weekly. Dams delivered and nursed pups. F_0 were evaluated for fertility and reproductive function, and were killed and necropsied at end of dosing period. Implantation sites were examined and histopathology was conducted. Litters were examined for external malformations, counted, sexed, weighed, and sacrificed and discarded on pd 6	0		9/10 females conceived	
		250	No effects	8/10 females conceived	
		500	No effects	7/10 females conceived	↓Pup weight on pd 1(7%)
		1000	↓Weight gain (21%) ↓ Testis and epididymis weight in F_0 males (14%) ↑Leydig cell hyperplasia and testicular degeneration	4/10 females conceived ↓Gestational weight gain (42%)	↓Live pups/litter at birth (n=2 vs 9) and pd 6 (n=1 vs 9) ↓Pup weight on pd 1 and 6 (29% and 43%)

WEB Table 15: BBP Reproductive Toxicity, Male Rats

Strain	Experimental Regimen	Number	Dose (mg BBP/kg bw/day)	Effects
F344/N Rat	Sub-chronic reproductive toxicity study (10wks).	15	0	
[NTP, 1997 #543]	BBP was administered in feed for 10 weeks prior to mating. Body weight and food intake were measured weekly.	15	20	NOAEL
		15	200	↓ Sperm concentration (30%)
	Each male was mated to 2 untreated females for 7 days. Reproductive parameters included fertility and fetal mortality. Males were then killed and examined for hematological, sperm, and histopathological effects. Females were killed and examined for corpora lutea and implantation sites on gestation day 13 or 13 days after mating.	15	2200	↓ Sperm concentration (>99%) Evidence of mating in 10/13 females; no pregnancies ↓Prostate and testes to bodyweight ratio ↓Epididymis and seminal vesicle weight Testicular and epididymal degeneration ↓Bodyweight gain (29%) ↑Liver and thymus to bodyweight ratio Mild macrocytic response anemia

WEB Table 14: BBP Reproductive Toxicity, Rats

Strain	Experimental Regimen	Number	Dose (mg BBP/kg bw/day)[b]	Effects
Wistar Rat	One generation reproductive toxicity study.	12(M)/ 21-20(F)[a]	0	
[TNO, 1993 #610]	BBP administered in feed 10 weeks and 2 weeks before mating in males & females, respectively, and throughout rest of study.	12(M)/ 17-22(F)	108 / 106 116 / 252	No effects
	Body weight and food intake measured weekly.	12(M)/ 20-21(F)	206 / 217 235 / 580	NOAEL
	One male and two females housed together for 3 weeks. Dams nursed pups through pnd 21. Study was repeated in the same rats.	12(M)/ 17-22(F)	418 / 446 458 /1078	↑ Liver to body weight ratios in F_0 females ↓ Weight gain of F_0 females during gestation and lactation ↓ F_1[b] pup weight on pd 21 (12%)
	Litters examined counted, sexed, and weighed. After weaning, F_1 examined for external abnormalities and sacrificed. F_0 were killed and necropsied. Histopathalogy on liver and reproductive tissue of control and high dose group.			No effects on implantations, reproductive organ morphology, or fertility, fecundity, and gestation indices

[a] Number of males and females delivering first and second litter, respectively
[b] Doses for males during premating / females during premating / females during gestation / females during lactation

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This is an early draft and the reference list may not be complete

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